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(54) Intravascular catheter with a nontraumatic distal tip

Intravaskularkatheter mit nichttraumatischer distaler Spitze

Cathéter intravasculaire avec extrémité distal non-traumétique

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Description

Background of the Invention

This invention generally relates to guiding catheters for use in intravascular procedures such as percutaneous transluminal coronary angioplasty (PTCA).

In classic PTCA procedures, a guiding catheter having a preshaped distal tip is percutaneously introduced into the cardiovascular system of a patient and advanced therein until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent the ostium of the desired coronary artery. The guiding catheter is twisted or torqued from its proximal end which extends out of the patient to turn the distal tip of the guiding catheter so that it can be guided into the coronary ostium. A guidewire and a dilatation catheter having a balloon on the distal end thereof are introduced into and advanced through the guiding catheter to the distal tip thereof, with the guidewire slidably disposed within an inner lumen of the dilatation catheter. The guidewire is first advanced out the distal tip of the guiding catheter, which is seated in the ostium of the patient's coronary artery, until the distal end of the guidewire crosses the lesion to be dilated. The dilatation catheter is then advanced out of the distal tip of the guiding catheter, over the previously advanced guidewire, until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion. Once properly positioned, the balloon is inflated to a predetermined size with radiopaque liquid at relatively high pressures (*e.g.*, generally 405,300 - 1,215,900 Pa (4-12 atmospheres)) to dilate the stenosed region of the diseased artery. The balloon is then deflated so that the dilatation catheter can be removed from the dilated stenosis and blood flow resumed therethrough. Further details of guiding catheters, dilatation catheters, guidewires, and the like used in angioplasty procedures can be found in U.S. Patent 4,323,071 (Simpson-Robert); U.S. Patent 4,439,185 (Lundquist); U.S. Patent 4,468,224 (Enzmann *et al.*); U.S. Patent 4,516,972 (Samson); U.S. Patent 4,438,622 (Samson *et al.*); U.S. Patent 4,554,929 (Samson *et al.*); U.S. Patent 4,582,185 (Samson); U.S. Patent 4,616,652 (Simpson); U.S. Patent 4,638,805 (Powell); U.S. Patent 4,748,986 (Morrison *et al.*); and U.S. Patent 4,898,577 (Badger *et al.*) which are hereby incorporated herein in their entirety by reference thereto.

Guiding catheters are frequently provided with soft distal tips in order minimize trauma to the arterial lining as the guiding catheter is advanced through an arterial passageway. See for example U.S. Patent 4,385,635 (Ruiz) which is incorporated herein by reference. Soft distal tips may reduce arterial trauma, but they do not always provide a smooth transition between the distal tip and the catheter shaft proximal thereto. Additionally, the soft distal tips are very difficult to locate fluoroscopically by the physician when guiding the distal tip into the ostium of the desired coronary artery. Another reference of note is EPA 0 303 487 which is considered to represent the closest prior art with respect to the present invention, and which discloses an intravascular catheter with a soft distal portion and distal radiopaque means attached thereto.

What has been needed and heretofore unavailable is a guiding catheter or other similar catheter with a nontraumatic distal tip which provides a smooth transition with the catheter shaft and is fluoroscopically observable by the physician in order to facilitate the advancement thereof through a patient's vasculature. The present invention satisfies that need.

Summary of the Invention

According to the invention an intravascular catheter is provided having: a tubular shaft having proximal and distal ends with an inner lumen extending therein;

a coaxially disposed flexible tubular portion secured to the distal end of the catheter shaft ; and
radiopaque means; the catheter being characterized by the tubular portion being made up of at least two relatively short, coaxially disposed flexible tubular elements, the most distal tubular element being softer than the proximal tubular element, the radiopaque means being a radiopaque material incorporated in the proximal tubular element.

The catheter of the invention generally includes an elongated tubular shaft having proximal and distal ends, an inner lumen extending therein and a flexible nontraumatic distal tip which is significantly softer than the catheter shaft to which it is secured. The nontraumatic distal tip has at least two, relatively short elastomeric or rubber-like tubular elements which are coaxially secured to the distal end of the tubular shaft. In a preferred form, the soft tip is designed with progressively stiffer elements in the proximal direction toward the tubular shaft so that when the tip contacts a blood vessel wall, the force thereof is transmitted to the tubular shaft in a transitionless manner, causing it to align with the flowline of the vessel. The most distal of the elastomeric tubular elements is softer and more pliable than the elastomeric tubular element proximally adjacent thereto and should have a durometer hardness of at least a Shore 10 A hardness less than the adjacent proximal tubular element. The proximal tubular element should have a durometer hardness of about a Shore 80 A to about a Shore 100 A and the distal tubular element should have a durometer hardness of about a Shore 70 A to about a Shore 90 A. The proximal elastomeric tubular element is formed with radiopaque material incorporated

therein to facilitate the fluoroscopic observation thereof when disposed within a patient's body lumen such as an artery.

The tubular shaft of the catheter is preferably of composite construction with an elongated braided tubular member formed from radially compressive multifilament polymeric strands, which is impregnated with a thermoset polymer and provided with an outer jacket of thermoplastic polymer. An inner lubricous liner formed of suitable lubricous material such as fluorinated ethylene propylene or polytetrafluoroethylene (*e.g.*, Teflon®, a registered trademark of E.I. du Pont, de Nemours & Co., Inc.) may be provided on the interior of the braided tubular member to thereby define the inner lumen extending within the catheter shaft.

To provide greater flexibility in the distal section of the catheter shaft, the distal section of the braided tubular member may be impregnated with a softer thermoset polymer than the thermoset polymer which impregnates the proximal section of the tubular braided member.

In one preferred embodiment the catheter of the invention is a highly torquable guiding catheter which is readily advanced within a patient's vascular system and, when torqued from the proximal end, it has little tendency to store energy along the length thereof and to release the stored energy by the sudden rotation of the distal end of the catheter, *i.e.* does not cause the distal end of the catheter to whip. Moreover, the composite structure of the catheter ensures that the circularity of the inner lumen thereof is maintained, so there is little likelihood that a guidewire or dilatation catheter will become bound-up within the lumen when the catheter passes through tortuous passageways. The elastomeric tubular elements forming the nontraumatic distal tip of the catheter are intended to minimize the risk of traumatic engagements with arterial linings and allows the distal tip to be fluoroscopically observable.

These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

Brief Description of the Drawings

FIG. 1 is an elevational view of a guiding catheter embodying features of the invention.

FIG. 2 is a transverse cross-sectional view of the catheter shown in FIG. 1 taken along the lines 2-2.

FIG. 3 is an enlarged longitudinal centerline cross-sectional view of the distal tip of the catheter shown in FIG. 1 taken along the lines 3-3.

FIG. 4 is an enlarged longitudinal centerline cross-sectional view of an alternate construction of the distal tip of a catheter embodying features of the invention.

FIG. 5 is a perspective view of the shaft of the catheter shown in FIG. 1 with sections exposed.

FIG. 5A is an expanded view of the braided section circled in FIG. 5.

Detailed Description of the Invention

FIGS. 1-5 and 5A schematically illustrate a guiding catheter 10 of the invention which generally includes an elongated catheter shaft 11 having a proximal section 12, a more flexible distal section 13, an inner lumen 14 extending therein, a Luer hub 15 on the proximal end of the shaft and a nontraumatic distal tip 16 comprising two relatively short elastomeric tubular elements 17 and 18 which are coaxially disposed. The distal section 13 of the shaft 11 is shaped to facilitate the entry thereof into the ostium of a desired coronary artery. As will be appreciated by those skilled in the art, the J-shape of the distal section 13 of the catheter shown in FIG. 1 is a schematic representation and a variety of shapes, such as the well-known Judkins and Amplatz configurations for both the right and left coronary arteries, may be employed to facilitate the entry of the distal tip of the guiding catheter into the ostium of the desired coronary artery. The relatively soft, nontraumatic distal tip 16 is intended to minimize traumatic engagement with arterial tissue.

FIGS. 2, 5 and 5A illustrate the composite construction of the shaft 11 of catheter 10. A thin-walled lubricous inner lining 20 is disposed within braided tubular element 21 and defines the inner lumen 14. The braided tubular element 21 is impregnated with a thermoset polymeric material and an outer jacket 22, preferably formed of a thermoplastic polymeric material, surrounds the exterior of the braided tubular element 21. The braided tubular element 21 is formed from a plurality of pairs of fibrous multifilament polymeric strands 23 and 24 which are radially compressed against the inner liner 20 when they are braided into the diamond-like pattern as shown in FIG. 5A.

The nontraumatic distal tip 16 of the catheter 10, as illustrated in FIG. 3, is comprised of two relatively short flexible tubular elements, a proximal element 17 and a distal element 18, and is butt joined to the distal end of shaft 11 by melt fusing or by a suitable adhesive, such as well-known cyanoacrylate-based adhesives, *e.g.* Loctite™ 405, sold by Loctite Corporation, Newington, Connecticut. Both tubular elements 17 and 18 are formed of elastomeric or rubber-like materials but the distal section 18 is softer and more flexible than proximal section 17. Additionally, the proximal section 17 has a radiopaque filler material incorporated therein such as bismuth trioxide in order to make the distal tip fluoroscopically observable within a patient. The short tubular sections 17 and 18 are also butt joined together by suitable means such as by heat fusing or by a suitable adhesive such as a cyanoacrylate-based adhesive, *e.g.* Loctite™ 405.

FIG. 4 illustrates a presently preferred construction for the nontraumatic distal tip 16 wherein the proximal tubular element 17 has a stepped construction which extends over a shoulder provided at the distal end of the shaft 11. Other-

wise, the distal tip is the same as described above for the embodiment shown in FIG. 3.

In one presently preferred embodiment of the invention, the inner lubricous lining 20 has a wall thickness of about 0.002 inch (0.051 mm), the braided tubular member 21 and the thermoset polymer matrix into which it is disposed has a wall thickness of about 0.003 inch (0.076 mm) and the outer jacket 22 has a wall thickness of about 0.005 inch (0.13 mm). The diameter of the inner lumen 14 extending within the inner lining 20 may range from about 0.06 to about 0.09 inch (1.5 - 2.3 mm). The overall length of the catheter 10 for coronary angioplasty may range from about 80 to about 125 cm.

The catheter shaft 11 is preferably manufactured by braiding a plurality of pairs of fibrous strands 23 and 24 onto the tubular inner liner 20 or, in the alternative, a mandrel (not shown) and then impregnating the fibrous braid with a thermoset polymeric material to form a tubular element 21. The distal section 13, which may be the most distal 5 to 20 cm of the shaft 11, may be impregnated with a thermoset polymer which cures to a softer material than that impregnating the proximal section 12 to provide a greater degree of flexibility to the distal section 13. In a presently preferred method of forming the product, a thermoplastic tubular member or sleeve which forms the outer jacket 22 is fit onto the impregnated, braided tubular element 21, and then a heat shrinkable tubular element (not shown) is fit over the thermoplastic tube forming the outer jacket 22 and the assembly is then heated to shrink the heat shrinkable tube and press the thermoplastic jacket 22 against the exterior of the braided tubular element 21 to secure the jacket thereto. Upon cooling, the heat shrinkable tube is slit along its length and then peeled off of the jacket 19.

The relatively short tubular elements 17 and 18 and the tip are butt joined together by suitable means such as fusion bonding to the distal end of the shaft 11. Luer hub 15 may be secured to the proximal end of the shaft 11. The distal section 13 of the catheter shaft 11 may be shaped to the desired configuration for its intended end use when the thermoset impregnate is cured or it may be heated and shaped after the catheter 10 has been made, for example, by the physician before the catheter is inserted into the patient.

One presently preferred thermoset polymer for impregnating the proximal section of the braided tubular element 21 is a polyurethane, such as two component polyurethane RP 6414-3 (resin and hardener) sold by the Ciba-Geigy Corporation and the presently preferred thermoset polymer for impregnating the distal end portion of the braided tubular element is also a polyurethane, such as two component polyurethane RP 6413-1 (resin and hardener) also sold by the same company. The resin/hardener ratios (by weight) for these polyurethane polymers are typically about 100/60. These polymers will cure at about 93°C (200 degrees F). or at room temperature. Preferably, the polymers are partially cured at an elevated temperature (e,g, 200 degrees F.) and then are allowed to completely cure at room temperature. other polymer systems such as epoxy based systems may also be used.

The thermoplastic jacket or coating 22 is preferably formed of a thermoplastic polyurethane made with a polytetramethylene glycol ether such 2363 55DE Pellethane which is available from the Dow Chemical Company or a polyurethane such as Texin-965 DM which is available from the Mobay Corporation.

The cured properties for the above polymers (7 days @ 25°C (77°F)) are set forth in the following table.

PROPERTY TESTED	METHOD OF TESTING (ASTM)	6413	6414	PELLETAN E 2363-55DE
DENSITY	D-792	1.06	1.08	1.15
HARDNESS	D-2224D	90-95A	55-65D	55D
TENSILE STRENGTH	D-638 (D-412)	17,236,892 Pa (2500 psi)	17,236,892 Pa (2500 psi)	44,815,920 Pa (6500 psi)
ULTIMATE ELONGATION	D-638 (D-412)	400%	250%	450%
TEAR STRENGTH	D-624	2,413,169.9 Pa (350 psi)	3,792,116.3 Pa (550 psi)	4,136,859.2 Pa (600 psi)
COMP SET	D-395	68%	89%	75%
TABER WEAR	D-1044 (C-501)	4.0 mg	8.6 mg	70(H-22)

The relatively short tubular elements 17 and 18 of the non-traumatic distal tip 16 of the catheter are preferably formed from aliphatic polyurethanes which are available from Thermedics Inc. of Woburn, Massachusetts under the trade name Tecoflex. A radiopaque grade of the Tecoflex resin, EG93A-HT60, is preferably used for the proximal section 17 and a softer nonradiopaque grade, EG80A, is preferably used for the distal section 18. Other grades of polyurethane, other elastomer systems and rubber-like materials may be employed.

The dimensions of the proximal and distal tubular sections of the non-traumatic distal tip varies depending upon the

dimensions of the catheter. Generally, the length of the tubular sections 17 and 18 is less than the outside diameter thereof. For most guiding catheters the length of the proximal radiopaque section 17 will be about 1 to about 10 mm, typically about 2 to about 2.5 mm, and the length of the distal section will be about 0.5 to about 4 mm, typically about 0.5 to about 1 mm. The outside diameters of both sections range from about 0.09 to about 0.15 inch (2.3 - 3.7 mm), typically about 0.1 inch (2.54 mm), and the inside diameters thereof range from about 0.07 to about 0.09 inch (1.78 - 2.3 mm), typically about 0.08 inch (2.0 mm). Greater or lesser dimensions may be used depending upon the particular end use of the catheter.

The multifilament polymeric fibrous strands employed to form the braided tubular element are preferably about 2500 mg/450 m to about 10.000 mg/450 m (50 to about 200 denier) and may be formed from a fibrous polymeric material such as aramid (*e.g.* Kevlar 49 sold by du Pont) and a polyester (*e.g.* Vectran). Other polymeric materials may be suitable. A 2x2 braid pattern shown in FIG. 5A is preferred and may be formed using 16 carriers with one bobbin per carrier. To facilitate the bonding of the polymer matrix which is incorporated into the braided tubular element 21 to a liner 20 formed of fluorinated ethylene propylene, the outer surface of the lining is etched with sodium naphthalene. In lieu of impregnating the braided tubular element after its formation with a thermoset plastic, in some instances it may be convenient to intermix thermoplastic fibers, such as polyester fibers, as adhesive with the multifilament fibers so that the tubular element is braided with the thermoset fibers incorporated therein. Heating of the braided tubular element will cure the incorporated polyester.

While the invention has been primarily described herein in terms of a guiding catheter with two relatively soft tubular elements forming the nontraumatic distal tip, it will be apparent to those skilled in the art that the distal tip may be formed from three or more of these relatively soft tubular elements with the durometer hardnesses thereof increasing in each element from the most distal element to the most proximal element. Moreover, the invention can be employed in a variety of intravascular catheters other than guiding catheters, such as peripheral guides and angiographic guides, other modifications and improvements can be made to the invention without departing from the scope thereof.

Claims

1. An intravascular catheter (10) having:

   a tubular shaft (11) with proximal (12) and distal (13) ends and an inner lumen (14) extending therein;
   a coaxially disposed flexible tubular portion secured to the distal (13) end of the catheter shaft (11); and
   radiopaque means, the catheter (10) **being characterized by**

   the tubular portion being made up of at least two relatively short, coaxially disposed flexible tubular elements (17, 18), the most distal (18) tubular element being softer than the proximal (17) tubular element, the radiopaque means being a radiopaque material incorporated in the proximal tubular element (17).

2. The intravascular catheter (10) of claim 1 **further characterized in that** the flexible tubular elements (17, 18) are formed of elastomeric or other rubber-like materials.

3. The intravascular catheter (10) of any one of the preceding claims **further characterized in that** the shaft (11) comprises:

   a braided tubular member (21) formed of a plurality of multifilament strands (23, 24) which are impregnated with a thermoset polymeric resin;
   a lubricous polymeric lining (20) extending longitudinally through the braided tubular member (21) and defining the inner lumen (14) extending within the elongated shaft (11) of the guiding catheter (10) ; and
   a thermoplastic polymeric jacket (22) on the exterior of the braided tubular member (21).

4. The intravascular catheter (10) of claim 3 **further characterized in that** the thermoset polymer resin which is incorporated into a distal (13) portion of the braided tubular member (21) has a cured hardness less than the cured hardness of the thermoset polymer resin which is incorporated into the proximal (12) portion of the braided tubular member (21).

5. The intravascular catheter (10) of claim 1 further characterized by the fact that the catheter (10) is a torquable guiding catheter (10) having an elongated tubular shaft (11) with the inner lumen (14) extending therein, the distal portion (13) being preformed with a soft distal tip (16) which facilitates a nontraumatic advancement through a patient's vasculature, the shaft (11) comprising:

   a braided tubular member (21) formed of a plurality of multifilament strands (23, 24) which are impregnated

with a thermoset polymeric resin, and

a thermoplastic polymeric jacket (22) on the exterior of the braided tubular member (21); and

a nontraumatic tip (16) secured to the distal (13) end of the elongated shaft (11) comprising the at least two relatively short elastomeric tubular elements (17, 18) in a coaxial configuration with each other and the elongated shaft (11).

6. The guiding catheter (10) of claim 5 **further characterized in that** the braided tubular member (21) is formed of radially compressed multifilament polymeric strands (23, 24) impregnated with thermoset polymeric resin.

7. The guiding catheter (10) of any one of claims 3 through 6 **further characterized in that** the thermoset polymeric resin which is incorporated into the braided multifilament polymeric strands (23, 24) is a polyurethane.

8. The guiding catheter (10) of any one of claims 3 through 7 **further characterized in that** the thermoplastic polymeric jacket (22) is a polyurethane.

9. The guiding catheter (10) of any one of claims 3 through 8 **further characterized in that** the multifilament strands (23, 24) are formed of a material selected from the group consisting of aramid and polyester.

10. The guiding catheter (10) of claim 5 **further characterized in that** the braided tubular member (21) has a distal (13) end which has incorporated therein a thermoset polymer resin having a cured hardness less than the cured hardness of the thermoset polymer incorporated into the braided tubular member (21) proximal (12) thereto.

11. The guiding catheter (10) of any one of claims 3 through 10 **further characterized in that** the multifilament polymeric strands (23, 24) are braided into a double strand, diamond shaped construction.

12. The guiding catheter (10) of claim 5 **further characterized by** a lubricous polymeric lining (20) extending longitudinally through the braided tubular member (21) and defining the inner lumen (14) extending within the elongated shaft (11) of the guiding catheter (10).

13. The intravascular catheter (10) of any one of the preceding claims **further characterized in that** the most distal tubular element has in durometer hardness of at least about Shore 10 A lower than the durometer hardness of the proximal tubular element.

14. The intravascular catheter (10) of any one of the preceding claims **further characterized in that** the distal tubular element has a durometer hardness of about Shore 70 A to about Shore 90 A.

15. The intravascular catheter (10) of any one of the preceding claims **further characterized in that** the proximal tubular element has a durometer hardness of about Shore 80 A to about Shore 100 A.

16. The intravascular catheter (10) of any one claim 1 **further characterized in that** the shaft (11) has an elongated polymeric inner member (20) defining the inner lumen (14) therein; an elongated intermediate tubular member (21) disposed about and secured to the inner tubular member (20) and formed of multifilament polymeric strands (23, 24) which are impregnated with a thermoset polymeric resin; and an elongated thermoplastic polymeric jacket (22) disposed about and secured to the intermediate tubular member (21).

17. The intravascular catheter (10) of claim 16 **further characterized in that** the plurality of multifilament strands are braided.

18. The intravascular catheter (10) of any one claim 1 **further characterized in that** the shaft (11) is a tubular member formed of a plurality of multifilament thermoplastic strands (23, 24) in a tubular structure (21) and impregnated with a thermoset polymeric resin; a thermoplastic polymeric jacket (22) disposed about and secured to the exterior of the tubular member (21); and a nontraumatic distal tip (16) formed of relatively soft elastomeric material and secured to the distal end (13) of the tubular member.

Patentansprüche

1. Intravaskularkatheter (10), umfassend:

einen rohrförmigen Schaft (11) mit einem proximalen Ende (12) und einem distalen Ende (13) und einem darin

verlaufenden inneren Lumen (14);

einen koaxial angeordneten flexiblen rohrförmigen Abschnitt, der am distalen Ende (13) des Katheterschaftes (11) angeordnet ist; und

eine röntgenstrahlenundurchlässige Einrichtung, wobei der Katheter (10) dadurch gekennzeichnet ist, daß

der rohrförmige Abschnitt aus mindestens zwei relativ kurzen, koaxial angeordneten flexiblen rohrförmigen Elementen (17, 18) besteht, wobei das am weitesten distal gelegene rohrförmige Element (18) weicher ist als das proximale rohrförmige Element (17), und die röntgenstrahlenundurchlässige Einrichtung ein in dem proximalen rohrförmigen Element (17) enthaltenes röntgenstrahlenundurchlässiges Material ist.

2. Intravaskularkatheter (10) nach Anspruch 1, des weiteren dadurch gekennzeichnet, daß die flexiblen rohrförmigen Elemente (17, 18) aus einem elastomeren oder anderen gummiartigen Material bestehen.

3. Intravaskularkatheter (10) nach einem der vorhergehenden Ansprüche, des weiteren dadurch gekennzeichnet, daß der Schaft (11) folgendes umfaßt:

ein geflochtenes rohrförmiges Element (21), das aus einer Vielzahl von multifilen Fäden (23, 24) besteht, die mit einem duroplastischen polymeren Harz imprägniert sind;

eine gleitfähige polymere Auskleidung (20), die sich in Längsrichtung durch das geflochtene rohrförmige Element (21) erstreckt und das innere Lumen (14) begrenzt, das in dem langgestreckten Schaft (11) des Führungskatheters (10) verläuft; und

einen thermoplastischen polymeren Mantel (22) auf der Außenseite des geflochtenen rohrförmigen Elements (21).

4. Intravaskularkatheter (10) nach Anspruch 3, des weiteren dadurch gekennzeichnet, daß das duroplastische polymere Harz, das in einem distalen Abschnitt (13) des geflochtenen rohrförmigen Elements (21) enthalten ist, eine Härte besitzt, die geringer ist als die Härte des duroplastischen polymeren Harzes, das in dem proximalen Abschnitt (12) des geflochtenen rohrförmigen Elements (21) enthalten ist.

5. Intravaskularkatheter (10) nach Anspruch 1, des weiteren dadurch gekennzeichnet, daß der Katheter (10) ein verdrehbarer Führungskatheter (10) ist, der einen langgestreckten rohrförmigen Schaft (11) mit einem darin verlaufenden inneren Lumen (14) aufweist, wobei der distale Abschnitt (13) mit einer weichen distalen Spitze (16) vorgeformt ist, aufgrund derer der Katheter leichter in nichttraumatischer Weise durch die Gefäße eines Patienten geschoben werden kann, wobei der Schaft (11) folgendes umfaßt:

ein geflochtenes rohrförmiges Element (21), das aus einer Vielzahl von multifilen Fäden (23, 24) besteht, die mit einem duroplastischen polymeren Harz imprägniert sind, und

einen thermoplastischen polymeren Mantel (22) auf der Außenseite des geflochtenen rohrförmigen Elements (21); und

eine nichttraumatische Spitze (16), die am distalen Ende (13) des langgestreckten Schaftes (11) befestigt ist, welches die mindestens zwei relativ kurzen elastomeren rohrförmigen Elemente (17, 18) in koaxialer Anordnung zueinander und zu dem langgestreckten Schaft (11) umfaßt.

6. Führungskatheter (10) nach Anspruch 5, des weiteren dadurch gekennzeichnet, daß das geflochtene rohrförmige Element (21) aus radial komprimierten multifilen polymeren Fäden (23, 24) besteht, die mit dem duroplastischen polymeren Harz imprägniert sind.

7. Führungskatheter (10) nach einem der Ansprüche 3 bis 6, des weiteren dadurch gekennzeichnet, daß das duroplastische polymere Harz, das in den geflochtenen multifilen polymeren Fäden (23, 24) enthalten ist, ein Polyurethan ist.

8. Führungskatheter (10) nach einem der Ansprüche 3 bis 7, des weiteren dadurch gekennzeichnet, daß der thermoplastische polymere Mantel (22) aus Polyurethan besteht.

9. Führungskatheter (10) nach einem der Ansprüche 3 bis 8, des weiteren dadurch gekennzeichnet, daß die multifilen Fäden (23, 24) aus einem Material bestehen, das ausgewählt ist aus der Gruppe umfassend Aramid und Polyester.

10. Führungskatheter (10) nach Anspruch 5, des weiteren dadurch gekennzeichnet, daß das geflochtene rohrförmige Element (21) ein distales Ende (13) besitzt, das ein duroplastisches polymeres Harz enthält, dessen Härte geringer ist als die Härte des duroplastischen Polymers, das in dem dazu proximalen (12) geflochtenen rohrförmigen Element (21) enthalten ist.

11. Führungskatheter (10) nach einem der Ansprüche 3 bis 10, des weiteren dadurch gekennzeichnet, daß die multifilen polymeren Fäden (23, 24) zu einem doppelsträngigen, rautenförmigen Gebilde geflochten sind.

12. Führungskatheter (10) nach Anspruch 5, des weiteren gekennzeichnet durch eine gleitfähige polymere Auskleidung (20), die sich in Längsrichtung durch das geflochtene rohrförmige Element (21) erstreckt und das innere Lumen (14) begrenzt, das in dem langgestreckten Schaft (11) des Führungskatheters (10) verläuft.

13. Intravaskularkatheter (10) nach einem der vorhergehenden Ansprüche, des weiteren dadurch gekennzeichnet, daß das am weitesten distal gelegene rohrförmige Element eine Durometerhärte besitzt, die um einen Wert von mindestens Shore 10 A niedriger ist als die Durometerhärte des proximalen rohrförmigen Elements.

14. Intravaskularkatheter (10) nach einem der vorhergehenden Ansprüche, des weiteren dadurch gekennzeichnet, daß das distale rohrförmige Element eine Durometerhärte von etwa Shore 70 A bis etwa Shore 90 A besitzt.

15. Intravaskularkatheter (10) nach einem der vorhergehenden Ansprüche, des weiteren dadurch gekennzeichnet, daß das proximale rohrförmige Element eine Durometerhärte von etwa Shore 80 A bis etwa Shore 100 A besitzt.

16. Intravaskularkatheter (10) nach Anspruch 1, des weiteren dadurch gekennzeichnet, daß der Schaft (11) ein langgestrecktes polymeres inneres Element (20) aufweist, welches das innere Lumen (14) begrenzt; ein langgestrecktes mittleres rohrförmiges Element (21), das um das innere rohrförmige Element (20) herum angeordnet und an diesem befestigt ist und aus multifilen polymeren Fäden (23, 24) besteht, die mit einem duroplastischen polymeren Harz imprägniert sind; und einen langgestreckten thermoplastischen polymeren Mantel (22), der um das mittlere rohrförmige Element (21) herum angeordnet und an diesem befestigt ist.

17. Intravaskularkatheter (10) nach Anspruch 16, des weiteren dadurch gekennzeichnet, daß die Vielzahl von multifilen Fäden geflochten sind.

18. Intravaskularkatheter (10) nach Anspruch 1, des weiteren dadurch gekennzeichnet, daß der Schaft (11) ein rohrförmiges Element ist, das aus einer Vielzahl von multifilen thermoplastischen Fäden (23, 24) in einer rohrförmigen Struktur (21) besteht und mit einem duroplastischen polymeren Harz imprägniert ist; wobei ein thermoplastischer polymerer Mantel (22) um die Außenseite des rohrförmigen Elements (21) herum angeordnet und daran befestigt ist; und wobei eine nichttraumatische distale Spitze (16) aus einem relativ weichen elastomeren Material besteht und am distalen Ende (13) des rohrförmigen Elements befestigt ist.

Revendications

1. Cathéter intravasculaire (10) comprenant :

   une tige tubulaire (11) pourvue d'extrémités proximale (12) et distale (13) et d'un conduit interne (14) s'étendant dans ladite tige ;
   une partie tubulaire flexible disposée coaxialement et fixée à l'extrémité distale (13) de la tige de cathéter (11) ; et
   des moyens radiopaques, le cathéter (10) étant caractérisé en ce que la partie tubulaire est réalisée à partir d'au moins deux éléments tubulaires flexibles, disposés coaxialement et relativement courts (17, 18), l'élément tubulaire le plus distal (18) étant plus mou que l'élément tubulaire proximal (17), les moyens radiopaques étant constitués par un matériau radiopaque incorporé dans l'élément tubulaire proximal (17).

2. Cathéter intravasculaire (10) selon la revendication 1, caractérisé en outre en ce que les éléments tubulaires flexibles (17, 18) sont réalisés dans des matériaux élastomériques ou d'autres matériaux comme le caoutchouc.

3. Cathéter intravasculaire (10) selon l'une quelconque des revendications précédentes, caractérisé en outre en ce

que la tige (11) comprend :

un élément tubulaire tressé (21) formé d'une pluralité de brins multifilamentaires (23, 24) qui sont imprégnés d'une résine polymérique thermodurcie ;
un chemisage polymérique lubrifiant (20) s'étendant longitudinalement à travers l'organe tubulaire tressé (21) et définissant le conduit interne (14) qui s'étend à l'intérieur de la tige allongée (11) du cathéter de guidage (10) ; et
une gaine polymérique thermoplastique (22) à l'extérieur de l'élément tubulaire tressé (21).

4. Cathéter intravasculaire (10) selon la revendication 3, caractérisé en outre en ce que la résine polymère thermodurcie qui est incorporée dans une partie distale (13) de l'élément tubulaire tressé (21) présente une dureté durcie inférieure à la dureté durcie de la résine polymère thermodurcie qui est incorporée dans la partie proximale (12) de l'élément tubulaire tressé (21).

5. Cathéter intravasculaire (10) selon la revendication 1, caractérisé en outre en ce que le cathéter (10) est un cathéter de guidage déformable (10) ayant une tige tubulaire allongée (11) dans laquelle s'étend un conduit interne (14), la portion distale (13) étant préformée avec une pointe distale molle (16) qui facilite l'avancement non traumatisant à travers le réseau vasculaire d'un patient, la tige (11) comprenant :

un élément tubulaire tressé (21) formé d'une pluralité de brins multifilamentaires (23, 24) qui sont imprégnés d'une résine polymérique thermodurcie, et
une gaine polymérique thermoplastique (22) à l'extérieur de l'élément tressé (21) ; et
une pointe non traumatisante (16) fixée à l'extrémité distale (13) de la tige allongée (11) comprenant au moins les deux éléments tubulaires élastomériques relativement courts (17, 18) dans une configuration coaxiale l'une par rapport à l'autre et par rapport à la tige allongée (11).

6. Cathéter de guidage (10) selon la revendication 5, caractérisé en outre en ce que l'élément tubulaire tressé (21) est réalisé avec des brins polymériques multifilamentaires compressés radialement et imprégnés d'une résine polymérique thermodurcie.

7. Cathéter de guidage (10) selon l'une quelconque des revendications 3 à 6, caractérisé en outre en ce que la résine polymérique thermodurcie qui est incorporée dans les brins polymériques filamentaires tressés (23, 24) est un polyuréthane.

8. Cathéter de guidage (10) selon l'une quelconque des revendications 3 à 7, caractérisé en outre en ce que la gaine polymérique thermoplastique (22) est un polyuréthane.

9. Cathéter de guidage (10) selon l'une quelconque des revendications 3 à 8, caractérisé en outre en ce que les brins multifilamentaires (23, 24) sont réalisés dans un matériau choisi dans le groupe des polyesters et des aramides.

10. Cathéter de guidage (10) selon la revendication 5, caractérisé en outre en ce que l'élément tubulaire tressé (21) comprend une extrémité distale (13) dans laquelle est incorporée une résine polymère thermodurcie présentant une dureté durcie inférieure à une dureté durcie du polymère thermodurci incorporé dans l'élément tubulaire tressé (21) proximale (12).

11. Cathéter de guidage (10) selon l'une quelconque des revendications 3 à 10, caractérisé en outre en ce que les brins multifilamentaires polymériques (23, 24) sont tressés suivant une structure en forme de losange à double brins.

12. Cathéter de guidage (10) selon la revendication 5, caractérisé en outre en ce que une chemise polymérique lubrifiante (20) s'étend longitudinalement dans l'élément tubulaire tressé (21) et définit un conduit interne (14) s'étendant dans la tige allongée (11) du cathéter de guidage (10).

13. Cathéter intravasculaire (10) selon l'une quelconque des revendications précédentes, caractérisé en ce que l'élément tubulaire le plus distal présente une dureté durométrique d'au moins environ 10° Shore inférieure à la dureté durométrique de l'élément tubulaire proximal.

14. Cathéter intravasculaire (10) selon l'une quelconque des revendications précédentes, caractérisé en outre en ce que l'élément tubulaire distal présente une dureté durométrique d'environ 70 à environ 90° Shore.

15. Cathéter intravasculaire (10) selon l'une quelconque des revendications précédentes, caractérisé en outre en ce que l'élément tubulaire proximal présente une dureté durométrique d'environ 80 à 100° Shore.

16. Cathéter intravasculaire (10) selon l'une quelconque des revendications précédentes, caractérisé en outre en ce que la tige (11) comprend un élément interne polymérique allongé (20) définissant à l'intérieur un conduit (14) ; un élément tubulaire intermédiaire allongé (21) disposé sur et fixé à l'élément tubulaire interne (20) et formé de brins polymériques multifilamentaires (23, 24) qui sont imprégnés d'une résine polymérique thermodurcie ; et une gaine polymérique thermoplastique (22) disposée sur et fixée à l'élément tubulaire intermédiaire (21).

17. Cathéter intravasculaire (10) selon la revendication 16, caractérisé en outre en ce que la pluralité de brins multifilamentaires est tressée.

18. Cathéter intravasculaire (10) selon la revendication 1, caractérisé en outre en ce que la tige (11) est un élément tubulaire constitué d'une pluralité de brins thermoplastiques multifilamentaires (23, 24) dans une structure tubulaire (21) et imprégnés d'une résine polymérique thermodurcie ; une gaine polymérique thermoplastique (22) disposée sur et fixée à l'extérieur de l'élément tubulaire (21) ; et une pointe distale non traumatisante (16) constituée par un matériau élastomérique relativement mou et qui est fixée à l'extrémité distale (13) de l'élément tubulaire.

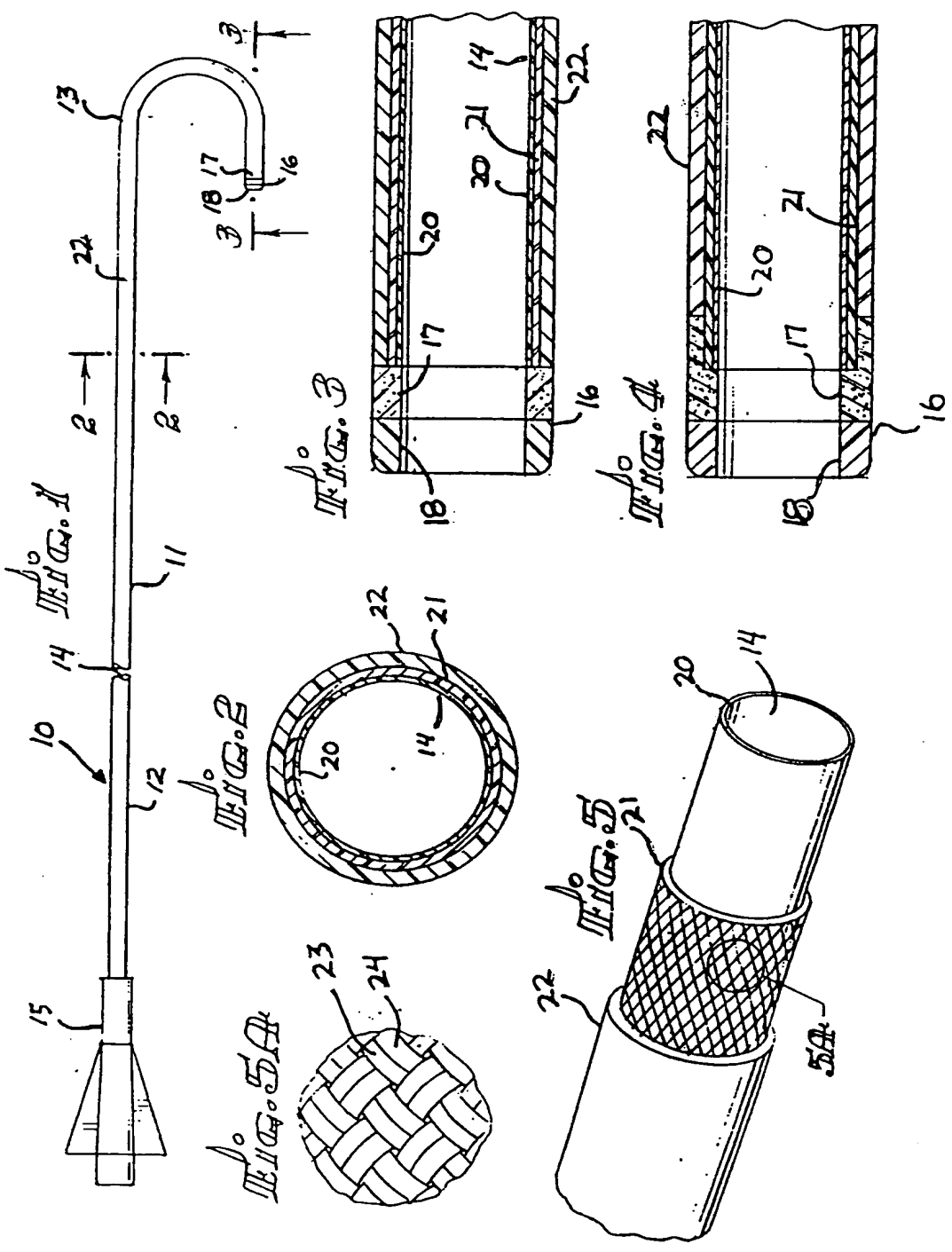
FIG. 1
FIG. 2
FIG. 3
FIG. 4
FIG. 5
FIG. 5A